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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,379	07/06/2001	Hing C. Wong	44470 C1-CPA-C (71758)	4293
21874	7590	03/21/2005	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			VANDERVEGT, FRANCOIS P	
			ART UNIT	PAPER NUMBER

1644

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/900,379	WONG ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 51-54 and 56-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-54, 56 and 59-61 is/are rejected.
- 7) ☒ Claim(s) 57 and 58 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

This application is a continuation of U.S. Application Serial Number 08/776,084, which is a continuation-in-part of U.S. Application Serial Number 08/382,454, which is a continuation-in-part of U.S. Application Serial Number 08/283,302.

Claims 1-50 and 55 have been canceled.

New claim 61 has been added.

Claims 51-54 and 56-61 are currently pending and are the subject of examination in the present Office Action.

In view of Applicant's amendment filed August 23, 2004, no outstanding grounds of rejection are maintained.

The following represents a new ground of rejection and necessitates that this Office Action be made NON-FINAL.

1. Applicant's arguments with respect to claim 51-54 and 56-60 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 51-54, 56 and 59-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to the genetic modification of an MHC fusion complex to include a terminal amino acid residue or residues with chemically reactive side chains. However, the specification only defines the term "chemically reactive" in terms of cysteine and histidine (see page 26, line 5 through page 27, line 16 for example).

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The specification provides no guidance regarding the meaning of the term “chemically reactive” beyond these two amino acid residues and the artisan would not be able to recognize that Applicant was in possession of other “chemically reactive” side-chained amino acid residues as part of the MHC class II complex construct. The Cys and His residues disclosed in the specification are well known in the art to form particular types of chemical bonds, with Cys residues capable of forming disulfide bridges between molecules and His residues capable of associating with nickel. However, the specification fails to disclose any other types of associations made by “chemically reactive side chain[s]” that are equivalent to those formed by Cys or His residues. While other types of amino acid residues are known in the art to have side chains that are “chemically reactive,” the specification fails to describe what types of reactivity are equivalent to the reactivity of the amino acid residues disclosed. The specification has failed to define the metes and bounds of the term “chemically reactive side chain” in a manner that would effectively convey to one of skill in the art that Applicant was in possession of a representative number of species defining the term. In other words, does the term “chemically reactive” also encompass heme-forming amino acid groups, copper association, hydrophobic interactions or antibody-antigen interaction? Without adequate description in the specification, the artisan would not be able to ascertain what types of “terminal amino acid residue(s) with chemically reactive side chains” are contemplated as part of the invention.

*Vas-Cath Inc. v. Mahurkar* ((CAFC, 1991) 19 USPQ2d 1111) clearly states that “Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See *Vas-Cath* at page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115).

The sole support for the recitation in the specification of “terminal amino acid residue(s) with chemically reactive side chains” is a single paragraph bridging pages 26 and 27 disclosing “chemically reactive side chains such as Cys or His” but without any clarification what types of reactivity qualify as “such as.” This is insufficient to support the recitation in the claims of “terminal amino acid residue(s) with chemically reactive side chains” as provided by the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 “Written Description” Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.”

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*Conclusion*

3. Claims 57 and 58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. *R*  
Patent Examiner  
March 11, 2005

*David A Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
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